Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 29, 2016 6:15 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Followup Request on Cost Considerations
Attachments: Markey.TSCA TA.Cost Effective.docx

Michal, in response to your request during the TA call, attached please find additional technical assistance on handling cost considerations.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information:

(i), the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(ii) a preference to impose restrictions under the rule that are cost-effective.

Commented [A1]: Compare 40 CFR 300.430 in National Contingency Plan: "The balancing shall also consider the preference for treatment as a principal element and the bias against off-site land disposal of untreated waste."

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, February 02, 2016 5:16 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on definition of processor
Attachments: Markey.TSCA TA.Definition of Process.docx

Michal,
The attachment provides TA responding to your request. Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, January 28, 2016 3:09 PM
To: Kaiser, Sven-Erik
Subject: TA request - definition of processor

Hi Sven

I have a couple questions about the definition of process/processor that have been raised by stakeholders.

1) First, there is a question about whether EPA could treat someone who took 10 gallon containers of a chemical substance and transferred the substance into smaller containers for sale as a processor? My read of the current statute is that YES, 10(A) would seem to allow this. Is that EPA's read as well and is there regulatory text that may further elaborate on the plain reading?
2) Second, what about companies who assemble things – ie install steering wheels in cars, or put furniture together? Could THEY be considered processors? My read is that 10(B) would NOT allow this, because if the chemical substance was already incorporated into the article, as it would be in the examples I used, (B) would make no sense in a reading that allowed these types of people to be treated as processors. Again, am I wrong on this, and is there any further regulatory or other elaboration on this point anywhere?

Thanks
michal

(10) The term ''process'' means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—
(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or
(B) as part of an article containing the chemical substance or mixture.
(11) The term ''processor'' means any person who processes a chemical substance or mixture.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building

Washington, DC 20510
202-224-2742

Connect with Senator Markey

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Current TSCA Definition of "Process"

(10) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

> (A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or
>
> (B) as part of an article containing the chemical substance or mixture.

Requests for TA

1) First, there is a question about whether EPA could treat someone who took 10 gallon containers of a chemical substance and transferred the substance into smaller containers for sale as a processor? My read of the current statute is that YES, 10(A) would seem to allow this. Is that EPA's read as well and is there regulatory text that may further elaborate on the plain reading?

- Yes, EPA has taken the view under current TSCA that the repackaging of a chemical substance (e.g., transferring from larger to smaller container) to prepare the chemical substance for sale may be viewed as "process[ing]" under § 3(10). The chemical substance is being prepared, after its manufacture, for distribution in commerce. See for example:
  - "Such mixing or repackaging of fibers is considered primary processing of bulk asbestos for the purpose of this rule." 47 FR 33198 (July 30, 1982)
  - "A processor is, among other things, one who prepares a chemical substance or mixture for distribution in commerce, after its manufacture, in the same or different form of physical state from that in which it was received by the processor (see TSCA section 3(10)). One who mixes, reacts, purifies, separates, repackages, or otherwise "prepares" a chemical substance or mixture for distribution in commerce is a processor." 50 FR 37182 (September 12, 1985)
  - "Processing—repackaging" among the reporting codes for the current Chemical Data Reporting rule. 40 CFR 711.15, Table 6.

2) Second, what about companies who assemble things – i.e., install steering wheels in cars, or put furniture together? Could THEY be considered processors? My read is that 10(B) would NOT allow this, because if the chemical substance was already incorporated into the article, as it would be in the examples I used, (B) would make no sense in a reading that allowed these types of people to be treated as processors. Again, am I wrong on this, and is there any further regulatory or other elaboration on this point anywhere?

- Regarding this second scenario, EPA has taken the view that a person who incorporates an article into other equipment, for distribution in commerce, may also be viewed as "process[ing]" the chemical substances in the articles, as that term is defined under TSCA. The assembly prepares the article for distribution in commerce, the chemical substances are themselves present "as part of an article," TSCA § 3(10)(B), and thus the chemical substances in the article are being prepared for distribution in commerce. See, for example, 40 CFR 750.31(a)(7) and (8) (regarding the assembly of equipment using PCB Articles).

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, December 03, 2015 7:20 PM
To: Michal Freedhoff
Subject: Sen. Markey TSCA TA on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions
Thanks,
Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and
b) The time to do so would not extend the PMN process beyond allotted 90-day deadline.

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.

EPA United States Environmental Protection Agency

Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

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Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 24, 2016 6:48 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on partial risk evaluations
Attachments: Markey.TSCA TA.Proceeding in phases.docx

Michal,
The attached TA responds to the request on partial risk evaluations. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 22, 2016 at 10:02:12 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on partial risk evaluations

Would this do it for you? I don't think a discussion about what you add below re cost considerations would be a constructive one. I am not sure that this works to address your concern re rules/deadlines though.

(3) (A) PRIOR-INITIATED **EVALUATIONS**[A1] .—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation [redacted], prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this Act[A2] .

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—
As relevant policies and procedures under this Act are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation [redacted] determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this Act.

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, March 21, 2016 6:25 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on partial risk evaluations

Michal,
This TA responds to your request on partial risk evaluations. Please let me know if any questions. Thanks,
Sven

For the partial RES you flagged for us last week, did EPA use costs when concluding unreasonable risk for those substances/uses? If EPA was forced to re-do elements of these REs, would the removal of costs and other non-risk factors alter the trajectory EPA feels these RES and rules is on such that it might make sense to delay their completion? Would EPA be proposing to go through with the RES and associated risk management for those uses using old definitions of unreasonable risk, cost considerations in rulemaking, and use of science? If EPA were planning to evaluate the additional uses of the substances, would EPA then plan to use the 'new-tsca' versions of these terms/considerations? Given the substances in question and their uses, would EPA expect to prioritize these substances and the rest of the uses not currently being considered by EPA soon, or has EPA in its view already addressed the real risks from these substances?

Response: EPA has completed risk assessments for 5 chemicals under the TSCA Workplan process. Those assessments only consider risk. There is no cost consideration. 3 of the chemicals have high risk and are moving to the risk management phase. We are developing proposed rules. As required by TSCA we will balance costs and benefits (the value of risk reduction) and identify the least burdensome means to reduce the risk. We are scheduled to propose rules for these three chemicals later this year.

The risk assessments for all three of these chemicals had narrow scopes. We did not look at all uses of the chemicals as would be required under both House and Senate passed bills. We assume that if a bill passes before we finalize these rules we would need to finalize them using the new rulemaking standard in the law. But because the risk assessments were done without consideration of costs, we would not need to redo the work for the uses which have already been assessed.

The issue we are flagging is that meeting the scoping intent of either bill would require a significant amount of additional work on these three chemicals to assess the uses that were not included in our final assessments. That could delay regulation of the uses with known risks. Modification of the cost considerations would take a little time but much less as the cost considerations under the current law are more onerous than either the House or Senate bills. If the Senate or House bill passed as drafted we would likely call these three chemicals high priority and make an argument that we can go forward with the narrower scoped regulations using the new standard. There is some legal vulnerability that we'd be prevented from doing so. Because the rulemaking deadlines in 6(c)(1) begin to run once EPA deems a chemical unsafe, EPA would be on a tighter time clock (4 years, as opposed to 3 years + 4 years) to both complete the risk evaluations AND any associated rulemakings with respect to other uses not part of the original evaluation. It is not clear to us whether those additional uses have risk. In the alternative, we could identify these three chemicals as high priority and then assess the additional uses before moving to risk management. The down side is that we would know there was risk for certain uses of these chemicals but we would be waiting to assess the remaining uses before doing any risk management.

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, March 20, 2016 11:16 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

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M

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Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

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To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Questions on partial risk evaluations

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Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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Re-title Section 26(j) as follows:

(j) POLICIES, PROCEDURES, AND GUIDANCE, AND CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

Renumber 26(j)(5) as 26(j)(6), and add the following after 26(j)(4):

(5) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

(A) With respect to chemical substances listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA has completed risk assessments prior to the date of enactment of the TSCA Modernization Act of 2015, the Administrator may conduct risk evaluations under section 6(b)(4) and publish proposed and final rules under section 6(a), as appropriate, based on the results of those risk assessments, notwithstanding the fact that the risk assessments the Administrator has completed for such chemicals did not evaluate all conditions of use. Any such risk evaluations shall evaluate the risks from the uses of the chemical substances that the Administrator assessed in the completed TSCA Work Plan risk assessments, to determine whether the chemical substances present an unreasonable risk of injury to health or the environment under those uses in accordance with section 6(b)(4), and any such rules shall ensure that the chemical substances do not present an unreasonable risk of injury to health or the environment, as that term is used in section 6(b)(4)(A), under those uses. In conducting such risk evaluations and proposing and promulgating such rules, the Administrator shall follow the deadlines and other requirements of sections 6(b)(4) and 6(c), as applied to the uses addressed in the rulemakings, with the deadlines running from the date of enactment of the TSCA Modernization Act of 2015.

(B) The Administrator shall subject any conditions of use that had not been considered in the completed risk assessments of these chemical substances to the processes and requirements of section 6(a), 6(b), and 6(c), as applied to those conditions of use.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, December 03, 2015 2:04 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on PBTs

Michal,
This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

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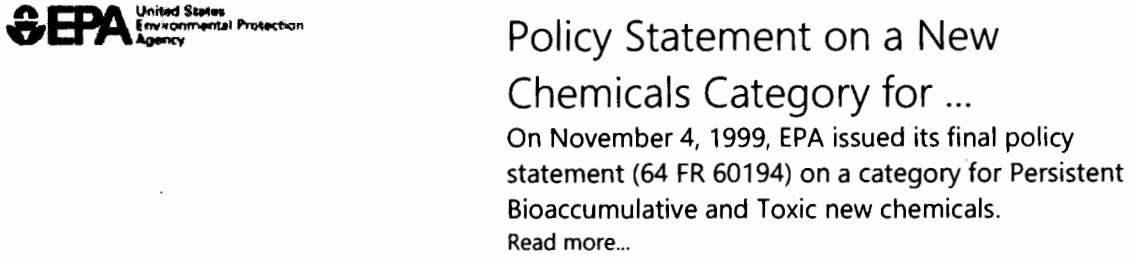

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey)
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 18, 2016 10:16 AM
To: Michal Freedhoff
Subject: Sen. Markey TSCA TA on section 4f
Attachments: Section 4(f) TA Feb 18, final.docx; ATT00001.htm

Michal,
Responding to your request, TA on section 4(f) attached. Please let me know if any additional questions.

Section 4(f) says "if EPA thinks something is super dangerous, regulate it quickly or tell everyone why there is no unreasonable risk".

Does EPA believe that it could decide not to regulate the super dangerous thing because it would be too expensive to do so, or does it believe that "unreasonable risk" is solely risk-based?

> **EPA Response: We believes that an unreasonable risk determination in section 4(f) of current TSCA would factor in costs as well as benefits. Such a determination would not be solely risk-based.**

Do you believe that the exclusion of costs in 4(f) that I sent you in the file yesterday in this section is needed to maintain consistency with the rest of the bill?

> **EPA Response: We believe the exclusion-of-costs language would be important to ensure consistency with the rest of the bill.**

Do you believe that, if we exclude costs as drafted in the document sent yesterday, that EPA would still be required to consider costs when developing regulatory action? If not, how would EPA draft 4(f) that 1) does not remove the words "unreasonable risk" and substitute another standard and 2) ensures that costs are considered as appropriate when regulating, but not when deciding WHETHER to regulate.

> **EPA Response: We believe that EPA would be required to consider costs when developing regulatory action to the extent cost consideration is required by section 5, 6 or 7 as modified by the Senate bill, even if cost is eliminated as a consideration under section 4(f). In fact, we believe the elimination of cost considerations from the unreasonable risk judgment in section 4(f) would be consistent with the usage of "unreasonable risk" in sections 5, 6 and 7. As we interpret those sections, and the definition of the safety standard in section 3, cost is not a factor in judgments about whether a risk is unreasonable. EPA must nonetheless consider cost in its risk management decisions. For example, under section 6, EPA would to consider cost and other factors in determining the most appropriate restrictions to eliminate any unreasonable risk, but the determination of whether any remaining risk is unreasonable would be made without regard to cost. In addition, under section 6, EPA could consider cost in deciding whether to issue exemptions under section 6(d)(5).**

We note that sections 5 and 6 in S bill now require an affirmative finding on the part of EPA. Would one solution be to end the sentence in 4(f)(2) after "5,6 or 7" and then go to "For good cause"?

> **EPA Response: Per the answer to the question above, we do not see a problem with the drafting that needs to be solved. And we believe implementation issues could be created by dropping the text you suggest from section 4(f). Without that text, EPA would be required to take action under section 5, 6 or 7 for every chemical for which information "*indicates* to the Administrator that there *may be a reasonable***

***basis* to conclude that [the] chemical substance or mixture presents or will present a *significant* risk of serious or widespread harm to human beings" (emphasis added). This finding is a tentative one, and the standard – significant risk – is different from "unreasonable risk". Thus, it is not clear that every chemical for which this tentative finding was made would be determined to warrant action under section 5, 6 or 7 upon more comprehensive review.**

More generally, has this provision ever been used and when?

EPA Response: EPA used this provision in 1984 for formaldehyde.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 07, 2016 1:27 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Section 5 costs and other non-risk factors
Attachments: Markey.TSCA TA.non-risk factors.docx

Michal,
The attached technical assistance responds to your request on TSCA section 5 considerations of costs and non risk factors. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of thee agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, February 27, 2016 9:07 AM
To: Kaiser, Sven-Erik
Subject: TA request - Section 5 costs and other non-risk factors

Sven

We understood from our call a couple weeks ago that EPA does not receive information about costs in PMNS and thus costs has never been part of an "unreasonable risk" determination for new chemicals. Thus, clarifying that such determinations should not consider costs would not alter current practice, but would remove legal ambiguity if costs are removed, say, in section 6.

We did not really talk about non-risk factors though. Things like whether the new chemical replaces another chemical that is known to be extremely dangerous, or whether there is some other benefit associated with the new chemical. Some have raised this as something they want EPA to be able to do.

Does EPA currently, or has it ever, considered non-risk factors as part of a PMN review or other action under section 5? Can EPA think of any non-risk factors that it would find beneficial to be able to consider under section 5? Would there be a downside to removing cost-consideration from section 5 unreasonable risk determinations, but leave non-risk factors implicitly in any 'unreasonable risk' determinations under section 5?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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Question:

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EPA Response:

The capacity of a chemical substance to displace a higher-risk chemical substitute in the marketplace is not a "non-risk" factor. The capacity of a chemical substance to be used in a manner that would "have some other benefit" may or may not be a "non-risk" factor, depending on what the benefit would be.

The extent to which EPA would be able to consider the kinds of factors you identify in the new chemicals context under the bills as currently drafted is not clear. On one hand, there is nothing in the text of the new chemicals provisions in the bills that would bar such consideration. On other hand, for the reasons explained below, we believe that the better reading of the risk evaluation provisions in section 6 of both bills is that they are based on the risks associated with the chemical itself, not those risks as compared to the risks associated with other chemicals. Thus, if the determination under S 697 as to whether a new chemical is likely to meet the safety standard is viewed as a prediction of the likely outcome of a full section 6 analysis, it may be argued that EPA cannot consider the risks posed by other chemicals in the new chemical analysis. Similarly, under the House bill, which does not amend section 5, it might be argued that EPA's determination as to whether a new chemical may present unreasonable risk under TSCA section 5(e) may not consider risks from other chemicals. Whether EPA could consider "some other benefit" associated with the chemical under either bill would likely depend on what the benefit is.

Here is why we think the better reading of the bills is that EPA's evaluations and determinations as to the safety of chemicals under section 6 is based on the risks of the chemicals under consideration, not a comparative risk judgment.

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S 697: Section 3A(h)(2)(C), which prescribes the content of safety assessments and determinations, provides that assessments and determinations must include "the hazards, exposures, and conditions of use of *the chemical substance"* ((ii)(I)(aa)), "the manner in which aggregate exposures. . . to *a chemical substance under the conditions of use* were considered" ((ii)(II)), and "the information regarding the impact on health and the environment of *the chemical substance*" ((ii)(IV)). There is no indication that the safety determination should contain information relating to other chemical substances. Although section 6(d)(4) requires EPA to consider, as part of the risk reduction rulemaking, one more feasible alternatives to the chemical substance, that consideration is part of the determination of "which restrictions to impose" (section 6(d)(4)(A)) in ensuring the chemical meets the safety standard and does not appear to factor into the standard itself. Moreover, the bill allows EPA to grant an exemption from section 6 rules where the use of the chemical "provides a substantial benefit to health, the environment, or public safety" (section 6(d)(5)(A)(ii)), suggesting that comparative risk should be factored into the exemption process, not into the determination of what is necessary to meet the safety standard. On the other hand, someone might argue that the establishment of two separate analytic steps prior to rulemaking – safety assessment and safety determination – means that Congress must have intended factors other than just the risk of the chemical (the basis for the assessment) to factor into the safety determination.

HR 2576: The House bill identifies the factors that EPA must consider in conducting a risk evaluation. Among other things, EPA must "integrate and assess information on hazards and exposures for all of the intended conditions of use of *the chemical substance*"(6(b)(4)(A)) and take into account various aspects of "exposures under the intended conditions of use of *the chemical substance*" (6(b)(4)(C). As with the Senate bill, there is no indication that EPA should consider risks from other chemical substances. In addition, it might be argued that one-step process in the House bill leading to rulemaking – risk evaluation – especially as contrasted with the Senate bill, demonstrates that Congress intended that only risk from the chemical can be factored in. Cutting the other way, though, is the fact that the House bill does not allow EPA to grant exemptions from section 6 rule requirements based on comparative risk (section 6(h)), which might lead to the argument that EPA must be able to consider comparative risk in the unreasonable risk determination.

EPA has on occasion, when developing the conditions for section 5(e) orders, taken into account the benefits that might accrue from replacing a riskier chemical already on the market with a new chemical that presents reduced risk, and EPA sees some value in being able to do this. If you wish to ensure that EPA can do that, the most straightforward way might be to add a provision in section 5 allowing EPA to consider comparative risk in developing new chemical restrictions, analogous to the comparative risk provision in section 6(d)(5)(A)(ii) of the Senate bill, which allows EPA to grant an exemption from section 6 rule requirements for a use of a

chemical substance that, "as compared to reasonably available alternatives, provides a substantial benefit to health, the environmental, or public safety." We cannot provide specific drafting suggestions that this point, in the absence of a specific version of section 5 to work off of.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 07, 2016 1:27 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Section 5 costs and other non-risk factors
Attachments: Markey.TSCA TA.non-risk factors.docx

Michal,
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Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Saturday, February 27, 2016 9:07 AM
To: Kaiser, Sven-Erik
Subject: TA request - Section 5 costs and other non-risk factors

Sven

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Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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The extent to which EPA would be able to consider the kinds of factors you identify in the new chemicals context under the bills as currently drafted is not clear. On one hand, there is nothing in the text of the new chemicals provisions in the bills that would bar such consideration. On other hand, for the reasons explained below, we believe that the better reading of the risk evaluation provisions in section 6 of both bills is that they are based on the risks associated with the chemical itself, not those risks as compared to the risks associated with other chemicals. Thus, if the determination under S 697 as to whether a new chemical is likely to meet the safety standard is viewed as a prediction of the likely outcome of a full section 6 analysis, it may be argued that EPA cannot consider the risks posed by other chemicals in the new chemical analysis. Similarly, under the House bill, which does not amend section 5, it might be argued that EPA's determination as to whether a new chemical may present unreasonable risk under TSCA section 5(e) may not consider risks from other chemicals. Whether EPA could consider "some other benefit" associated with the chemical under either bill would likely depend on what the benefit is.

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EPA has on occasion, when developing the conditions for section 5(e) orders, taken into account the benefits that might accrue from replacing a riskier chemical already on the market with a new chemical that presents reduced risk, and EPA sees some value in being able to do this. If you wish to ensure that EPA can do that, the most straightforward way might be to add a provision in section 5 allowing EPA to consider comparative risk in developing new chemical restrictions, analogous to the comparative risk provision in section 6(d)(5)(A)(ii) of the Senate bill, which allows EPA to grant an exemption from section 6 rule requirements for a use of a

chemical substance that, "as compared to reasonably available alternatives, provides a substantial benefit to health, the environmental, or public safety." We cannot provide specific drafting suggestions that this point, in the absence of a specific version of section 5 to work off of.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, February 19, 2016 4:14 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on section 5 prioritization and restrictions
Attachments: Markey.TSCA TA.Section 5 - prioritization and restrictions.docx

Michal,
Attached is TA responding to your questions on section 5 of the Senate bill on: 1) prioritization, and 2) restrictions. We are working on the remaining section 5 question on scope of preemption. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This technical assistance is provided by EPA in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1. There is a provision in Senate Section 5 (below) that seems to say "EPA can use its prioritization and/or section 6 authority even after taking action under section 5". I don't see where this was ever really a question. Can you comment on whether this language solves a real problem or concern?

(f) Further evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

(1) a notice of commencement for a chemical substance under subsection (e); or

(2) new information regarding the chemical substance.

EPA Response: Without this provision, it is already clear that EPA can prioritize an existing chemical substance (previously reviewed under the new chemicals program) under § 4A where there is both new information and an NOC. Similarly, it is already reasonably clear that EPA should not be prioritizing a new chemical substance (previously reviewed under the new chemicals program) under § 4A where there is neither new information nor any NOC. Section 4A is generally directed at prioritizing existing chemical substances. § 4A(a)(1).

In the scenario where EPA receives an NOC for a chemical substance, but no other new information, this provision clarifies that EPA is allowed to prioritize the chemical substance under § 4A, even though EPA hasn't received any other new information that wasn't considered when EPA reviewed the chemical under the "likely to meet," standard. The introduction of this clarification into § 5(f) was probably unnecessary. The § 5(d) "likely to meet," standard is distinct from a prioritization for the full § 6 safety determination and there does not appear to be any obstacle built into § 4A that would otherwise preclude the prioritization of a substance that completed review under § 5(d).

However, in the scenario where EPA receives new information about a chemical after the new chemical review period has lapsed, but before EPA receives an NOC for the chemical, this provision seems to provide that EPA is allowed to prioritize the chemical substance under § 4A. This would not be clear without § 5(f), since § 4A(a)(1) generally refers to "existing" chemical substances and the chemical in question would be a new chemical, since there has been no NOC.

If the drafters ultimately decide to delete § 5(f), it will be important to clearly state the grounds for the deletion in the legislative history, to avoid unintentional signaling that Congress is repudiating a principle for which § 5(f) is merely superfluous. Specifically: the principle that EPA is allowed to prioritize a chemical substance under § 4A, previously reviewed under § 5(d), after the new chemical becomes an existing chemical (following the submission of an NOC)

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2. Senate section 5 lists the types of restrictions EPA can take in response to a determination that a new chemical needs to be restricted (below). In EPA's view, does it require such specificity in order to take any of these measures? I know the list is derived from the Section 6 analogue, but the basis for my question is that EPA has been imposing restrictions under Section 5 without this list for some time.

C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—
(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;
(ii) a requirement that manufacturers or processors of the chemical substance—
(I) make and retain records of the processes used to manufacture or process the chemical substance; or
(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;
(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—
(I) in general; or
(II) for a particular use;
(iv) a prohibition or other restriction of—
(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;
(II) any method of commercial use of the chemical substance;
(III) any method of disposal of the chemical substance; or
(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—
(I) in general; or
(II) for a particular use.

EPA Response: EPA does not require a statutory litany of inclusions, beyond the authority already conferred in §5(d)(4)(A) to "prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal" of a chemical substance, in order to implement § 5(d)(4). The inclusions at § 5(d)(4)(C) could actually be construed as a subset of the § 5(d)(4)(A) authority, and thus could actually be construed as *narrowing* EPA's authority through their presence.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 2:35 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Section 8
Attachments: Markey.TSCA TA.section 8.docx

Michal,
This responds to your TA request on section 8.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 4:15 PM
To: Kaiser, Sven-Erik
Subject: Section 8

Sven

Attached is a redline of Senate section 8 with a few changes from the reported text. Could you have your team take a look and address any issues? This can be at the back of the current queue.

Thanks
Michal

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 01, 2016 9:30 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request - cost considerations - pls accelerate response
Attachments: TA on revised cost-effectiveness language 3-1 OGC.docx; ATT00001.htm

Michal,
The attachment responds to your follow up TA request on cost considerations. Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 1, 2016 at 5:39:28 AM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - cost considerations - pls accelerate response

Sven

Attached is a proposal that is similar to option #2 you looked at in that TA document we were discussing yesterday (the one that contained 4 options - option #2 was the one that was incrementally more prescriptive than 697).

It adds cost-effectiveness in a different way - intended not to be as directed as either the option we discussed yesterday or the 2 versions of 2576 that are also in the other TA document.

Does EPA believe this option a) works and b) adds to the analytic burden and litigation risk as compared to old option #2 (and if so, how)?

Quick turnaround appreciated. Thanks.

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Does EPA believe this option a) works

Yes, EPA believes this provision could be implemented. EPA would need to establish whether or not the restrictions in the rule are cost-effective in order to implement "(A) Public Availability," but this analysis would be "under paragraph (1)" and thus bounded by considerations of practicability and reasonably available information. Whether or not the restrictions are found to be cost-effective would control whether EPA has a further duty to include additional descriptive analysis in the administrative record. A key difference with old options ## 3 and 4 relates to whether the necessity discussion is framed as a free-standing determination (as in options ## 3 and 4) or as an integral part of the justification of the proposed rule (as in your draft). Given that the rejection of more direct language on determining cost-effectiveness would be part of the legislative history, Courts would likely construe your proposed text as a signal to give a slightly greater degree of discretion to EPA on the finding (of cost-effectiveness or necessity) than would be afforded under the House bill.

and b) adds to the analytic burden and litigation risk as compared to old option #2 (and if so, how)?

Yes, this language adds to analytic burden relative to old option #2. EPA would need to decide whether the restrictions in the rule were cost-effective, which was not a decision mandated under old option #2. Note also that this language apparently requires EPA to determine whether *each restriction* is cost-effective, not whether the rule as a whole is cost-effective; option #2 in contrast appears to require analysis of the rule as a whole. Furthermore, if a restriction were not cost-effective, EPA would need to develop an analysis of an indeterminate number of alternatives in order to decide whether the restrictions were nonetheless necessary (again, though, bounded by the practicability and reasonable availability limitations).

Yes, this rule adds to the litigation risk relative to old option #2. EPA would need to defend decisions that particular restrictions are cost-effective, or nonetheless necessary, whereas it would not need to do so under old option #2. It is possible, but it cannot be predicted with confidence, that this formulation would entail less litigation risk than old option #3 (i.e., the slightly modified version of House language on cost effectiveness).

Some additional observations:

1. **We note that the inclusion of "mixtures" in this language – which is in TSCA section 6(c) but not in the cost-consideration provisions of either bill – may cause confusion, since section 6 rulemaking under the bills appears to be limited to chemical substances that have been found to present unacceptable risk, not to mixtures per se.**
2. **As the text is reorganized from S 697, (d)(1)(D)(ii) seems awkward, since it is not clear how the costs and benefits of alternative regulatory action would be relevant to the economic consequences of the regulatory action actually selected.**

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 11:12 AM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your follow up TA questions regarding the revised fee language.

To protect or decide to release CBI that was included in a risk evaluation or test data?
- Yes

To use the results of the test when conducting the risk evaluation or doing risk management?
- Yes

Industry-requested REs and whether the fees for the RE could then be used for rulemaking?
- Yes

Also, we suggest the following revisions to the fees language to better clarify what chemical substances or mixtures we are talking about. Also the proposition should be "defray the cost . . . **of**" not "for".

"Defray the cost of administering the provision for which such fee is collected and of any other activities under the Act related to the chemical substance or mixture that is the subject of the data submission or risk evaluation ~~for which such fee is collected~~"

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 5:05 AM
To: Kaiser, Sven-Erik ; Black, Jonathan (Tom Udall) ; Deveny, Adrian (Merkley)
Subject: Re: Sen. Markey TSCA TA request - House fees

Quick follow up question for you Sven

Would changing "defray the cost of administering the provision for which suhc fee is collected" to

"Defray the cost of administering the provision and any other activities under the act related to the chemical substance or mixture for which such fee is collected" address one of the points you make below?

Would this change above allow you to protect or decide to release CBI that was included in a risk evaluation or test data, for example? Would it allow you to use the results of the test when conducting the risk evaluation or doing risk management?

I recognize that the solution above probably does not address the core resubstantiation obligations provided in the senate bill in section 8. But could it address the question of industry-requested RES and whether the fees for the RE could then be used for rulemaking?

Quick turnaround needed - mtg on this is at 1:30. Feel free to suggest alternatives if what I wrote makes no sense. :-)

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
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Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall) ; Deveny, Adrian (Merkley)
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 18, 2016 10:39 AM
To: Michal Freedhoff
Subject: Sen. Markey TSCA TA request - House section 6(b)

Michal,
This responds to your TA request on House section 6(b). We issued a data needs assessment for the brominated phthalates flame retardant cluster fo this reason. We expect there will be other examples going forward.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

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Washington, DC 20460

202-566-2753

. **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

> **Date:** February 13, 2016 at 9:50:09 AM EST
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: TA request - House section 6(b)**
>
> Sven
>
> Are there any workplan chemicals that could not meet the 6(b) risk finding without additional testing/information? I know House 6 does not require it to be made for workplan chemicals - I'm just asking because alternative formulations that do require it to be made are being discussed.
>
> Thanks
>
> Michal
>
> Michal Ilana Freedhoff, Ph.D.
> Director of Oversight and Investigations
> Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 18, 2016 2:15 PM
To: Freedhoff, Michal (Markey)
Cc: Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - ITC

Michal, This TA responds to your request on the ITC. Please let me know if any questions. Thanks,
Sven

Have they recommended chemicals for testing that EPA didn't decide to test?
Yes. Over the years of TSCA implementation a number of chemicals were removed from the Priority Testing List (those recommended or designated by the ITC) by the ITC after further development of data and/or discussion by the ITC. In those cases, the rationale for removing them from the list is described in the relevant ITC report. Reasons have included the fact that testing or information which meets the need is already available or was otherwise being developed; investigation revealed that the chemical was no longer actively in commerce; or that the testing/data development recommended could be better provided by another federal entity. There are a number of recommended chemicals on the current list for which EPA has not yet required testing or proposed to the ITC for removal.

Does it function as intended?
The ITC has provided a forum for dialogue among federal agencies about testing and data needs related to chemicals. However, some of the procedures specified in TSCA have limited its usefulness. For instance, the statutory list of members does not include some key agencies (e.g., HHS/FDA and CPSC) and includes some who have been inactive. In addition, the ITC is not a FACA but a committee of federal employees representing their agencies (as opposed to their personal expertise). Nonetheless, TSCA imposes conflict of interest requirements on individual federal employees which has made it difficult to recruit members; in particular experienced senior staff from other agencies. The Senate bill and the House offer have provisions that appear to achieve the same outcome in terms of requiring EPA to consider the recommendations of other agencies, without the procedural difficulties and overhead required by current TSCA.

Is it an active body?
Yes, the Interagency Testing Committee (ITC) still exists and meets twice a year to review federal data needs for chemicals to add to the Priority Testing List (PTL). Although the ITC did meet on a semi-annual basis in 2014-15, it did not recommend any changes to the PTL. As a result, no report was published.

On Mar 16, 2016, at 2:50 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Can you get us some history of the ITC's work? Have they recommended chemicals for testing that EPA didn't decide to test? When/what? Does it function as intended? Is it an active body?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, February 19, 2016 1:15 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - more on section 4, SEnate 4(a)

Michal,
This responds to your TSCA section 4(a) TA request.

1) Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority". Does EPA view "regulatory testing needs" as the agency/office needs to be considering regulation? Going back to the example of the WVA spill, when clearly EPA would not have been thinking about listing that chemical for regulation under SDWA, does EPA believe it still could have requested testing?

EPA Response: Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority." This doesn't mean that the requesting authority needs to have already initiated rulemaking proceedings before they can request a test. We think "regulatory testing needs," represent a broader concept than that. They would include any information about the chemical substance that would help the requesting authority to later exercise (or decide whether to exercise) its legal powers to manage risks relating to that chemical substance. Thus, in the case of a chemical spill, any EPA office thinking about using one of its non-TSCA legal authorities to address the spill, and needing more information for that purpose, could use section 4(a)(1)(D).

2) Has EPA ever required TSCA testing outside a regulatory need? For example, if EPA wanted to do some testing to assist researchers, public health officials or local communities or to inform product stewardship/decisions, I'm assuming it really couldn't do so under Senate section 4, and could only do so if it could meet the risk finding in House section 4 (or one of the other criteria in TSCA 4(a). Has it ever required testing that falls into these categories?

EPA Response: Again, EPA understands "regulatory testing needs," broadly. EPA has not used TSCA to require chemical testing that was unnecessary for any regulatory purpose. Risk-relevant chemical information sought by researchers, public health officials, local communities, and product stewardship authorities would very plausibly also be within the scope of the regulatory testing needs of a variety of authorities implementing non-TSCA Federal law. If there was indeed a request from such an authority, EPA could use its testing authority under Senate 4(a)(1)(D). EPA could also use its testing authority under Senate 4(a)(2) if it wanted to decide whether or not the chemical that was the subject of such outside interest was a high or low priority chemical substance under TSCA. Under the House bill, with respect to the chemical of outside interest, EPA would need to make a "may present" an unreasonable risk finding, a substantial exposure/release finding, or have met the standard for commencing a risk evaluation (also "may present" an unreasonable risk) in order to require testing.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey)
Sent: Tuesday, February 16, 2016 4:39 PM
To: Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)
Subject: TA request - more on section 4, SEnate 4(a)

Sven – some additional follow ups for you guys on section 4.

1) Senate 4(a)(1)(D) "allows for testing at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority". Does EPA view "regulatory testing needs" as the agency/office needs to be considering regulation? Going back to the example of the WVA spill, when clearly EPA would not have been thinking about listing that chemical for regulation under SDWA, does EPA believe it still could have requested testing?
2) Has EPA ever required TSCA testing outside a regulatory need? For example, if EPA wanted to do some testing to assist researchers, public health officials or local communities or to inform product stewardship/decisions, I'm assuming it really couldn't do so under Senate section 4, and could only do so if it could meet the risk finding in House section 4 (or one of the other criteria in TSCA 4(a). Has it ever required testing that falls into these categories?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 22, 2016 5:00 PM
To: Michal Freedhoff
Subject: Sen. Markey TSCA TA request - risk finding to initiate risk evaluations under section 6

Michal,
Alternative 2 is the higher bar. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 11, 2016 at 12:00:32 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request - risk finding to initiate risk evaluations under section 6

Sven
I'd like EPA's view on which formulation represents a higher bar to initiating a risk evaluation, and why. Thanks.
Michal

Alternative 1:

A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether the chemical substance may present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance; or

Alternative 2:

"(A) In general.—Not later than 6 months after the receipt of information under paragraph (3) for a chemical substance, the Administrator shall determine, using the process developed under paragraph (6);

"(i) whether there exists the potential that the chemical substance presents or will present an unreasonable risk of injury to human health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use, and shall identify such substances as high-priority substance for risk evaluation. The Administrator shall publish for public notice and comment the scope of the risk evaluation to be conducted for any such chemical substance;

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 17, 2016 11:14 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request - Section 4, parties to testing

Michal,
This TA responds to your followup request. Please leg me know if any additional questions. Thanks,
Sven

Simply striking "order, or consent agreement" from 4(b)(2)(A) wouldn't restore sense to the paragraph. Respecting rules issued under subsection (a), there would still remain a problem with 4(b)(2)(B) directing the reader to non-existent finding provisions ((a)(1)(A)(ii) and (a)(1)(B)(ii)).

More broadly, paragraph (4)(b)(2) is structured as a constraint on EPA's discretion to identify the scope of persons who would be subject to testing requirements for a particular rule, order, or consent agreement. Since the paragraph is a constraint on authority, it is not necessary in order for EPA to exercise its underlying testing authorities. Striking the paragraph would give EPA broad authority to require entities to conduct testing – including entities that are not manufacturers or processors of the chemical. Whether you should strike or update the paragraph depends on your the policy objectives.

On Feb 12, 2016, at 5:32 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Sven
This is in reference to the EPA TA that pointed out that Section 4(b)(2) in what I sent you doesn't work with Senate 4(a). Would it make sense to strike "order or CA" and then leave the provision related to rule authority? Is it necessary to specify who EPA can direct to test things at all (ie should we strike the whole thing)?

(2)(A) A rule, order, or consent agreement under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule, order, or consent agreement under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding de-scribed in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

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Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, February 26, 2016 10:43 AM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - Section 12 Exports

Michal – this responds to your technical assistance request on TSCA section 12 on exports. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Q: Other than fixing the "unreasonable risks" in section 12 (and the Hg language added en route to the Floor), does EPA see any workability or other problems associated with leaving section 12 the way it is in existing statute rather than the changed version in 697?

EPA Response: We believe you have identified the main workability problem that would arise in integrating existing section 12 with the provisions of a revised TSCA: the confusion that could occur if the section 12(a) standard (currently "unreasonable risk") does not conform with the standard for regulation prescribed in the revised statute. Beyond that, citations will likely need to be conformed. For example, section 12(b) refers to requirements to submit data under section 5(b), but the data submission requirements of current section 5(b) would be deleted from S 697. Thus, any final assessment of the language of section 12 would have to be made in light of changes to other portions of the statute.

Beyond workability issues, it might be argued that some of the changes made to section 12 by S 697 – especially some of the changes in section 12(b) -- are in the nature of conforming changes and should logically be made. The logic of section 12(b) of TSCA is that persons exporting or intending to export chemicals for which EPA has taken some action evincing a potential risk concern should give notice to EPA, so that EPA can notify the receiving country. In current section 12(b), the triggering EPA actions are the imposition of requirements to submit data under section 4 of 5(b), the issuance of an order under section 5, the proposal or promulgation of a section 5 or 6 rule, and court actions under section 5 or 7. It might be argued for example that an EPA determination that a chemical substance does not meet the safety standard under S 697, or that a new chemical substance is not likely to meet the safety standard, warrants notification by the same logic as the EPA actions identified in the current section 12(b).

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 11:33 AM
To: Kaiser, Sven-Erik
Subject: TA request - section 12

Sven

Other than fixing the "unreasonable risks" in section 12 (and the Hg language added en route to the Floor), does EPA see any workability or other problems associated with leaving section 12 the way it is in existing statute rather than the changed version in 697?

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, February 24, 2016 12:11 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - section 4/5 nexus

Michal,
This responds to your TA request on section 4/5 nexus.

The bill does not specify that a test order or rule, issued solely because it was necessary to review a PMN notice, would cease to have effect if the PMN were later withdrawn. Therefore, such an order/rule would not necessarily and immediately cease to have legal effect under such circumstances.

However, EPA already has sufficient authority under the bill to incorporate a contingency provision into the test order or rule, whereby that order/rule would automatically expire if the PMN were withdrawn. Even if EPA elected not to include such a provision, the withdrawal of the PMN would mean that EPA would have no rational basis to refuse a request to correspondingly withdraw the test rule/order (i.e., assuming that no other grounds for the testing had since become apparent).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 1:44 PM
To: Kaiser, Sven-Erik
Subject: TA request - section 4/5 nexus

Sven

In section 4, epa can issue test orders for purposes of reviewing a PMN. In section 5, we say that PMNS can be withdrawn. What if the PMN is withdrawn before the testing is completed - what happens to the test order? Do we need to build in a withdrawal of the test order into section 5 for that circumstance?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 25, 2016 2:48 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - section 5/6 PBTs

Michal,
This responds to your technical assistance request on PBTs in sections 5 and 6 PBTs. EPA sees an advantage to referencing the 2012 TSCA Work Plan Chemicals Methods document in the PBT provisions of sections 5 and 6. Doing so would enable EPA to act on PBT chemicals more expeditiously, as opposed to developing a new scoring process.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 4:29 PM
To: Kaiser, Sven-Erik
Subject: TA request - section 5/6 PBTs

Hi Sven

Sections 5 and 6 both key to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 when prescribing which PBTs should be subject to the provisions. There is a concern that a) since prioritization will hopefully make the Workplan cease to exist at some point in the future and b) EPA may want to change the way it scores PBTs based on new scientific methodology etc, we may want to find a different way to reference this document. The options we have discussed include:

TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 **(or a successor Methods Document)**

Or just saying

For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, ~~pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012~~, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that....

Does EPA see advantages or disadvantages to either formulation given the policy objectives, or is there a 3rd option we should consider instead?

Thanks
Michal
Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 25, 2016 2:48 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - section 5/6 PBTs

Michal,
This responds to your technical assistance request on PBTs in sections 5 and 6 PBTs. EPA sees an advantage to referencing the 2012 TSCA Work Plan Chemicals Methods document in the PBT provisions of sections 5 and 6. Doing so would enable EPA to act on PBT chemicals more expeditiously, as opposed to developing a new scoring process.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 4:29 PM
To: Kaiser, Sven-Erik
Subject: TA request - section 5/6 PBTs

Hi Sven

Sections 5 and 6 both key to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 when prescribing which PBTs should be subject to the provisions. There is a concern that a) since prioritization will hopefully make the Workplan cease to exist at some point in the future and b) EPA may want to change the way it scores PBTs based on new scientific methodology etc, we may want to find a different way to reference this document. The options we have discussed include:

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Or just saying

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Thanks
Michal
Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 15, 2016 4:24 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - senate 14(f)(2)(A)(iv)

Michal – This responds to the TA request on CBI – Senate 14(f)(2)(A)(iv). Please let me know if any additional questions. Thanks,
Sven

This provision seems to allow EPA to disclose CBI if EPA would find doing so useful in conducting risk evaluations or writing 6(a) rules. I'm having a hard time understanding when this might be true and why, if EPA needed assistance with RE'S or rules, it could not contract with experts who could sign confidentiality agreements rather than disclosing CBI to everyone.

Response:
- TSCA has provisions that allow EPA to share CBI with contractors who have gone through the CBI security process.
- In developing risk evaluations or rules, EPA could use studies that include CBI. In some instances, this could inhibit public comment/external review on the complete basis for the assessments or rules. This provision would give EPA the discretion to share CBI for these purposes.

Does EPA currently make CBI public for this sort of reason?

Response:
- In instances where broader access to essential data elements in a study has been needed to further public comment, EPA has been successful in having companies voluntarily declassify data elements.

Does EPA believe that it could contract with academics or others who might be of help to EPA?

Response:
- EPA contracts with entities who support our work on evaluations, reviews, and regulation development so they would be allowed access to CBI if they been provided clearance after the TSCA CBI security process. If they are not under contract to EPA, we do not have the ability to share CBI data.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 11:13 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - senate 14(f)(2)(A)(iv)

This provision seems to allow EPA to disclose CBI if EPA would find doing so useful in conducting risk evaluations or writing 6(a) rules. I'm having a hard time understanding when this might be true and why, if EPA needed assistance with RE'S or rules, it could not contract with experts who could sign confidentiality agreements rather than disclosing CBI to everyone.

Response:
- TSCA has provisions that allow EPA to share CBI with contractors who have gone through the CBI security process.
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Does EPA believe that it could contract with academics or others who might be of help to EPA?

Response: EPA contracts with entities who support our work on evaluations, reviews, and regulation development so they would be allowed access to CBI if they been provided clearance after the TSCA CBI securitiy process. If they are not under contract to EPA, we do not have the ability to share CBI data.

Anything I'm missing about this provision?

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, January 14, 2016 4:39 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - "substantial evidence"

Michal – This responds to your TA request. EPA does not believe that a risk evaluation that concludes that a substance does NOT pose an unreasonable risk would be judicially reviewable under substantial evidence under the House bill. The House bill does not amend the judicial review provision of TSCA (section 19) to subject such determinations to section 19. As such we believe they would be reviewable in federal district court under the general federal 6 year statute of limitations under an arbitrary and capricious standard, rather than in a US court of appeals, within the 60 day limit specified in section 19, under a substantial evidence standard. Note that even section 19(a) were amended to bring review of these determination under section 19, they would be reviewable under the arbitrary and capricious standard unless section 19(c)(1)(B)(i) were also amended to add these determinations to the list of specific EPA actions that are subject to substantial evidence review.

The TA does not necessarily reflect the policy positions of the agency and the administration on the bills and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, January 14, 2016 1:54 PM
To: Kaiser, Sven-Erik
Subject: TA request - "substantial evidence"

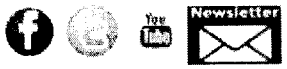
Sven

Does EPA believe that a risk evaluation that concludes that a substance does NOT pose an unreasonable risk would be judicially reviewable under substantial evidence under the House bill? I have believed that the requirement to have a notice and comment period on risk evaluations and to make them final agency actions was intended to do that, but someone just observed to me that risk evaluations are not specifically required to be rules in the House bill and it is just 6(a) rules that are pulled into substantial evidence in the judicial review section –what is your team's take?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 21, 2016 1:54 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request - timeframes

Michal,
This TA responds to your request on timeframes.

I was not involved when the various timeframes for EPA activities were selected and don't know what their basis was. Where did a 3 year risk evaluation timeframe come from? Could it be shorter without straining EPA's ability to meet its deadlines? How much shorter? What about 1 year to complete a priority designation given what that entails in the Senate offer?

Response: The three year timeline for risk evaluation developed from EPA's experience with conducting risk assessments under current TSCA. Given that the scope of assessments under the Senate bill would include all uses of a chemical – and that our current assessments are more limited in scope – reducing the timeframe would likely endanger EPA's ability to meet the timeline.

EPA does think that the one year timeline for designating a priority chemical, as described in section 6(b)(3), is achievable.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** March 19, 2016 at 1:18:39 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: TA request - risk evaluations**
>
> Sven
>
> This is for Monday anytime (and if you need longer that's fine, just let me know - don't mess w anyone's weekend).
>
> I was not involved when the various timeframes for EPA activities were selected and don't know what their basis was. Where did a 3 year risk evaluation timeframe come from? Could it be shorter without straining EPA's ability to meet its deadlines? How much shorter? What about 1 year to complete a priority designation given what that entails in the Senate offer?
>
> Thanks
> Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 15, 2016 1:13 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, January 05, 2016 3:55 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on cost considerations
Attachments: Markey.TSCA TA.Cost Considerations.docx

Michal,
In response to your request, please see the attached TA. Please let me know if any additional questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, December 15, 2015 4:26 PM
To: Kaiser, Sven-Erik
Subject: TA - cost considerations in a rule

Sven

I'm attaching a document that lists in one place 4 different ways to factor costs into rulemaking. EPA has seen all of these before. I am trying to determine the following:

1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?
2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

S 697

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

MERGED HOUSE/SENATE PROPOSAL (ALTERNATIVE TO HOUSE COST LANGUAGE)

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.**—In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator **shall factor in the following considerations, and publish a statement describing how they were factored into the rule—**

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

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(D)~~)~~ the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health;~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

H 2576 AS MODIFIED USING EPA TA

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

H 2576

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

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	Burden relative to baseline	**Litigation Risk**
S. 697 (d)(4) Analysis requirements	**Lowest Analytical Burden (Tied) Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.

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	Burden relative to baseline	**Litigation Risk**
H.R. 2576, entirely dropping "cost-effective" paragraph (B) but modifying (A) above per new Senate Proposal	**Lowest Analytical Burden (Tied) Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Second Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
H.R. 2576 paragraph (B) as modified	**Intermediate Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Third Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
H.R. 2576 paragraph (B) status quo	**Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Saturday, March 12, 2016 11:30 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on House passed bill section 14 CBI

Michal, this responds to your request for TA on the section 14 CBI provisions in the House bill as passed. Separately I will send TA on section 14 CBI in the House offer. Please let me know if any questions. Thanks, Sven

House Bill as passed
CBI
Section 14(b)(1) as revised would protect the confidentiality of chemical formulas, including molecular structures, in health and safety studies, which would result in the protection of specific chemical ids. This would curtail the release of chemical ids in health and safety studies, which are releasable under current section 14 unless they reveal process information.

Section 14(b)(1)(C) requires EPA to provide notice to the submitter of impending release of information claimed as CBI, unless "a request for renewal is granted under subparagraph (B)." But subparagraph (B) does not require EPA to grant a renewal request; it merely requires that a request be submitted.

The bill gives EPA authority to provide CBI to state and local governments when necessary (section 14(a)(5)). That said, EPA would not be able to disclose CBI to state and local governments as quickly as it can disclose CBI in the other circumstances identified in section 14(a). TSCA generally imposes a 30-day period following notification before EPA can disclose CBI, but it creates an exception to this waiting period for information disclosed under the grounds specified in section 14(a). The bill would not add disclosure under section 14(a)(5) to the list of exceptions (although it would add disclosure to responders and health professionals under the new section 14(a)(6)).

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** March 11, 2016 at 5:48:50 PM EST
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: RE: Sen. Markey TSCA TA Request on section 14**
>
> Actually I was looking for TA on HOUSE section 14 if you have it. Thanks.
>
> Michal Ilana Freedhoff, Ph.D.
> Director of Oversight & Investigations
> Office of Senator Edward J. Markey
> 255 Dirksen Senate Office Building
> Washington, DC 20510
> 202-224-2742

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 11, 2016 1:10 PM
To: Michal Freedhoff
Subject: Sen. Markey TSCA TA request on merged test section
Attachments: 402-10-16MFtoDK OGC.doc; ATT00001.htm

Michal, please see the responsive TA attached. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 10, 2016 at 7:47:32 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: TA request - Section 4

Sven

Can your team look at the attached and tell me if you have concerns about workability or drafting or anything else? You've seen much of this before, and some has been the subject of earlier TA. Would be great to get anything you have back by noon tomorrow. Ignore animal testing as you will have nothing new to say on that – what I'm looking for is your thoughts on this merged H-S construction.

Thanks

Michal

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS

(1) IN GENERAL. - The Administrator may, by rule, order, or consent agreement, require **testing** to develop new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that [there is a reasonable basis for concern about the potential risk of the substance or mixture, and] the information is necessary -

(A) to review a notice under section 5(d) or to perform a risk evaluation under section 6;

(B) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);

(C) pursuant to section 12(a)(4); or

(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

(A) IN GENERAL.—**Except as provided in paragraph (5),** the Administrator may **[in limited circumstances,]** require the development of new information for the purposes of prioritization under section 6.

(B) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

(C) PRIORITIZATION DECISION BY THE ADMINISTRATOR - Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, consent agreement or order issued under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance.

(3) STATEMENT OF NEED - When requiring testing to develop new information relating to a chemical substance or mixture, the Administrator shall identify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

[(4) REQUIREMENT - In determining whether to require testing to develop new **information**, the Administrator shall consider the exposure level or exposure potential of chemical substance or mixture, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential.]

(5) The Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced

Commented [GB1]: The Senate bill changes this title to refer to development of new information, not testing. Assuming the intent is to allow EPA to require development of exposure-related data along with toxicity date (which it seems to be), the senate wording seems preferable so as not to create arguments over what constitutes testing (e.g., an argument that tesing is for tox purposes, and is distinct from monitoring, which is for exposure purposes.

Commented [GB2]: Same comment about use of "testing"

Commented [GB3]: Presumably this would be married to something like the House version of section 6, since this citation would be wrong under the senate bill.

Commented [GB4]: This citation would be correct under the senate bill but not the house bill. Will not point out further citation issues, under the assumption that other portions are in flux.

Commented [GB5]: Why is this limitation stated here and not in (1)? Does paragraph 5 not apply to testing for para 1 purposes? In any event, this proviso seems unnecessary, since paragraph 5 applies according to its own terms.

Commented [GB6]: This suggests there are limitations beyond the described in B. Could create arguments as to what those limitations are.

Commented [GB7]: Consistent with our first comment, above, consider adding "toxicity" before "information", to avoid the implication that testing is only or principally about toxicity, which could arise from the requirement to consider potential exposure (but not potential toxicity) before requiring testing.

testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.
(6) Testing required under paragraph (1) shall not be required for the purpose of establishing or implementing a minimum information requirement.

Commented [GBS]: But testing under paragraph 2 can be required for this purpose? Presumably the intent was to cite to both paragraphs?

s.—If the Administrator finds that—
(1)(A)(i) the manufacture, distribution in commerce, pro-cessing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
(C) testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and
(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;
the Administrator by rule, order, or consent agreement require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(b)(1) TESTING REQUIREMENT RULE, ORDER, OR CONSENT AGREEMENT.—A rule, order, or consent agreement under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule, order, or consent agreement,

(B) test protocols and methodologies standards for the development of test data for such substance or mixture,

including specific reference to any reliable non-animal test procedures; and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or consent agreement under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment.

The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules, orders, and consent agreements under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(32)(A) A rule, order, or consent agreement under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph

(B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(C) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule, order, or consent agreement under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

Commented [GB9]: B now refers to protocols and methodologies, not standards. Make change throughout.

Commented [GB10]: Should not be set off as a new clause – this is part of the text of A.

Commented [GB11]: Should be B

Commented [GB12]: This subparagraph (C), from existing TSCA, does not work in the bill, because the citations refer to existing TSCA provisions that have been stricken, and EPA can't make all manufacturers and processors test under an order or CD – the Agency can only make the parties test.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(4) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order or consent agreement under subsection (a) requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, **except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission; (B) a transcript shall be made of any oral presentation; and** (C) the Administrator shall make and publish with the rule a statement describing the information required in paragraphs (2) and (3) of subsection (a), the findings described in paragraph (1)(A), (1)(B) or (1)(CB) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) EXEMPTION.—(1) Any person required by a rule or order under sub-section (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which data are being developed pursuant to such a rule, order or consent agreement ~~a rule under subsection (a) or for which~~ data is being developed pursuant to such a rule, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been

Commented [GB13]: Note that this perpetuates TSCA's extra procedures, beyond the APA, for test rules. Although not the best readingof the language, this could give rise to an argument that EPA should use orders sparingly, so as not to deprive manufacturers and processors of these rights.

Commented [GB14]: 1. Note that this provision imposes the requirements on rules only, not orders. 2. What does this add? Para (3) already requires a statement, for rule and orders. And para (2) doesn't actually require information – the requirement to explain the choice of an order is in (3).

submitted o the Administrator in accordance with such rule, order, or consent agreement or which is being development pursuant to such rule, order, or consent agreement ~~such rule or which is being developed pursuant to such rule~~,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule or order with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period—

(i) beginning on the date such data is submitted in accordance with a rule, order, or consent agreement ~~promulgated~~ under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule, order, or consent agreement ~~promulgated~~ under

subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, order or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule, order, or consent agreement with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any test data pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

(e) Reduction of Testing on Vertebrates.—

(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—

(i) toxicity information;

(ii) computational toxicology and bioinformatics;

(iii) high-throughput screening methods and the prediction models of those methods; and

(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

(B) encouraging and facilitating—

(i) the use of integrated and tiered testing and assessment strategies;

(ii) the use of best available science in existence on the date on which the test is conducted;

(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

(vi) the submission of information from—

(I) animal-based studies; and

(II) emerging methods and models; and

(C) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the

21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

(i) the substance cannot be absorbed; or

(ii) testing for a specific endpoint is technically not practicable to conduct; or

(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

(4) VOLUNTARY TESTING.—

A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to

develop information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).

(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the sub-stance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the

preceeding[1] sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of eight members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

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[1] So in law. Probably should be "preceding".

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any test data required to be submitted under this Act, or

(2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable, without taking into account costs or other non-risk factors. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the

Commented [GB15]: Should be protocols or methodologies, throughout here.

date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial.

[(h) Transparency – Subject to Section 14, the Administrator shall make available to the public all rules, consent agreements and orders and all information submitted under this section."]
[15 U.S.C. 2603]

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the fourth sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".

Commented [MF16]: Move to 26?

Commented [GB17R16]: Seems better to retain here. Seems best not to add section-specific provisions into section 26.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, 5~~(b)~~(4), or 6, or an order in effect under section 4 or section 5(de)(4), or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7, to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

(i) review the adequacy of the standards prescribed according to subparagraph (B);

(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted; and

(iii) revise the standards if the Administrator so determines.

Commented [A1]: This mandatory periodic review, including two comment periods, will likely have little or no value, since the new 8(a)(4) authority appears to allow EPA to collect anything it could collect under 8(a)(1), with no small business exemption. Overall, we think there might be confusion about the relationship of 8(a)(1) and (a)(4).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(4) RULES.—

(A) DEADLINE.—

(i) IN GENERAL.— Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of additional information known or reasonably ascertainable by the person making the report, including rules applicable to processors, so that the Administrator has the information necessary to carry out this title.

(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

(i) to limit the potential for duplication in reporting requirements;

(ii) to minimize the impact of the rules on small manufacturers and processors; and

(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific

Commented [A2]: It might make sense to change the title of section 8(b) from "Inventory" to "Inventories", since it will contain two completely unrelated inventories (the TSCA Inventory and the Mercury Inventory under 8(b)(10).

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experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System (SDANS) published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

(iii) treat all components of categories that are considered to be statutory mixtures under this Act, when present as components of such mixtures, as being included on the list established under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation--

(I) cement, Portland, chemicals, CAS No. 65997-15-1;

(II) cement, alumina, chemicals, CAS No. 65997-16-2;

(III) glass, oxide, chemicals, CAS No. 65997-17-3;

(IV) frits, chemicals, CAS No. 65997-18-4;

(V) steel manufacture, chemicals, CAS No. 65997-19-5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402-68-4; and

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—In the event that existing guidance allows for multiple nomenclature conventions, the Administrator shall—

(I) maintain the nomenclature conventions for substances;, and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list established under paragraph (1); and

(bb) permits persons to rely on that new guidance for purposes of determining whether

Commented [A3]: The drafting here is imprecise, especially since the items in the list are chemical substance, not mixtures. (In the past, EPA called these chemical substances "statutory mixtures" but this terminology is not current practice, is generally confusing, and is unnecessary to accomplish the intended policy objective of ensuring that these substances remain on the Inventory exactly as they were described in 1985.) It is unhelpful to blur the basic definitional terms "chemical substance" and "mixture," which are elsewhere defined as separate concepts by statute. This could lead to debate elsewhere about the operation of TSCA (e.g., whether EPA can or must do safety assessments on mixtures).

The addition of the phrase "when present as components of such mixtures," does not fully clarify matters, because it does not address when a particular combination of substances would qualify as one of these listed substance. There is, in fact, nothing under "this Act" that sheds light on this question. The answer is found in the TSCA Inventory listings for the chemical substance. Therefore, EPA recommends the following redraft, which will more clearly accomplish the apparent policy objective of this language: **"treat all chemical substances described by the following category listings, when manufactured as described in Appendix A of column I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a), as being . . ."**

Commented [A4]: We assume that this refers only to EPA guidance, and suggest clarification. Additionally, EPA is unaware of any existing EPA guidance that allow for multiple nomenclature conventions, meaning that these provisions would be completely inoperative. Nonetheless, note that the SEPW Report on p. 20, states that "numerous nomenclature conventions exist that they may prevent the efficient distribution of chemicals into commerce." EPA does not understand what the report is alluding to, complicating our interpretation of this language.

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a chemical substance is on the list established under paragraph (1);

(ii) MULTIPLE CAS NUMBERS.—**For any chemical substance appearing multiple times** on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

(4) CHEMICAL SUBSTANCES IN COMMERCE.—

(A) RULES.—

(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and allow processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

(iv) LIMITATION.—No substance on the list published under paragraph (1) shall be removed from such list by reason **of the implementation of this subparagraph, or be subject to Section 5 of this Act by reason of a change to active status under paragraph (5)(B).**

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating the rule established pursuant to subparagraph (A), the Administrator shall—

(i) maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14 submit a notice under subparagraph (A) that includes such request;

~~require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published~~

Commented [A5]: SEPW Report on page 20 suggests that the general objective is to allow new substances "similar" to existing chemical substances to be treated as existing chemical substances. Note that it has not been EPA's practice or interpretation of TSCA to treat substances substances that are similar in some respect to substances on the inventory as the same chemical substances, and EPA does not believe this practice would be consistent with standard chemical nomenclature conventions. Thus, if this language is not wholly inoperative, it will be the subject to considerable interpretive debate.

Commented [A6]: This language would never become operative. At such time as EPA determined that a single chemical substance appeared twice on the TSCA Inventory, EPA would delete the duplicate entry, thereby not triggering the statutory duty.

Commented [A7]: It would be clearer to say by reason of being designated an inactive chemical substance under this subparagraph.

Commented [A8]: Note that this means EPA cannot treat the re-activation of a chemical substance as a prompt to issue a SNUR for that substance. Was that the objective?

If the objective is simply to reassure industry that being moved back to active would not require the submission of a PMN, that should be clear simply from the prior sentence, which makes clear that the chemical was never removed from the list of existing chemical substances in the first place.

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~~under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and~~

(iii) require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C); and

(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific identity of the substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

(D) REQUIREMENTS OF REVIEW PLAN.—Under the review plan under subparagraph (C), the Administrator shall—

(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

(ii) in accordance with section 14—

(I) review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, ~~modify~~approve in part, or deny each claim; and

(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case

Commented [A9]: What is EPA supposed to do with inactive chemical substances for which no request was received to maintain an existing claim for protection against disclosure?

Under (ii) there was an obligation for any such claimant to submit a re-substantiation notice of their claim that the Chem ID is confidential. Would the consequence of failure to do so be that they waive their claim and the chemical is also moved to the non-confidential portion of the inventory?

Is yes, why is that excluded from discussion here?
If no, what was the point of the original requirement that they submit a re-substantiation notice?

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the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(iii) encourage manufacturers or and processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

(E) TIMELINE FOR COMPLETION OF REVIEWS.—

(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

(ii) CONSIDERATIONS.—

(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources.

(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

(5) ACTIVE AND INACTIVE **SUBSTANCES**.—

(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

(B) CHANGE TO ACTIVE STATUS.—

(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

Commented [A10]: Unlike other provisions of the bill under which EPA is given authority to specify the manner of CBI assertion and substantiation, there is no such authority here. If the intent is for EPA to have such authority, it could be added.

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(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, ~~modify~~approve in part, or deny the claim;

(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

(C) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

(7) PUBLIC INFORMATION.—Subject to this subsection, the Administrator shall make available to the public—

(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

(i) an active substance; or

(ii) an inactive substance;

(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

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(C) subject to subsections (f) and (g) of section 14, the specific identity of any active substance for which—

(i) a claim for protection against disclosure of the specific identity of the active ~~chemical~~ substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;

(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive ~~chemical~~ substance for which a notice is received under paragraph (4)(A)(i) or (5)(CB)(i) that is not on the confidential portion of the list published under paragraph (1).

(9) **CERTIFICATION.**—Under the rules promulgated under this subsection, manufacturers and processors shall be required—

(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.

(10) MERCURY.—

(A) DEFINITION OF MERCURY.—In this paragraph, **notwithstanding section 3(2)(B),** the term 'mercury' means—

(i) elemental mercury; and

(ii) a mercury compound.

(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

(i) identify any remaining manufacturing processes or products that intentionally add mercury; and

(ii) recommend actions, **including proposed revisions of Federal law (including regulations), to achieve further reductions in mercury use.**

(D) REPORTING.—

(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

Commented [A11]: Note that the "rules required under this subsection" will include the mercury rule EPA promulgates under the new 8(b)(10)(D), added by section 29 of the bill. So this certification will be required for submission under that rule as well as under the preceding inventory rules.

Commented [A12]: This seems unnecessary and has potential negative implications for EPA's interpretation of the MEBA provisions already codified in TSCA sections 6 and 12. EPA has interpreted those provisions as covering even mercury that does not qualify as a chemical substance under section 3(2)(B) of TSCA, and the inclusion of the notwithstanding clause here could call that interpretation into question. Also, the bill does not add a "notwithstanding" provision in the mercury amendments relating to section 12(c).

Commented [A13]: It is not clear what EPA is supposed to do here with respect to regulations. Is the intent that EPA recommend proposed regulations? Are we making that recommendation to ourselves? And does the bill give EPA additional rulemaking authority for this purpose?

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(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

(iii) EXEMPTION.—This subparagraph shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

Commented [A14]: EPA has interpreted the existing MEBA provisions codified in sections 6 and 12 as generally not covering mercury waste. There is some concern that the specific exemption here in 8(b) will call that general interpretation into question.

(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—

(1) IN GENERAL.—Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who

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obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(2) ADDITIONAL INFORMATION.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health or the environment.

(f) DEFINITIONS.—~~For purposes of this section,~~ In this section:

(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

(C) for which a notice is received under subsection (b)(5)(CB).

(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

(3) MANUFACTURE; PROCESS.—The terms "manufacture" and "process" mean manufacture or process for commercial purposes.

[15 U.S.C. 2607]

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 25, 2016 2:43 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Section 8/14 - false claims on CBI

Michal,
This responds to your technical assistance request on false CBI claims. We assume that by "false CBI claims" you mean a CBI claim for which there is no basis despite such basis having been asserted.

Neither TSCA as currently written nor S. 697 provide authority for action under TSCA based on a false CBI claim. The new requirements in S. 697 regarding how a CBI claim is asserted do result in statements which, if in violation of the False Statements Act, 18 USC 1001, could be the basis for criminal prosecution under that statutory provision. Such prosecution would be done by the Department of Justice. We are not aware of any instance in which the Department of Justice has pursued action under section 1001 regarding false statements pertaining to TSCA CBI claims.

While there theoretically could be enforcement action under TSCA section 15 for not submitting the statements required under section 14 as amended, we do not see any authority in TSCA itself for enforcing against someone who makes one of those statements knowing that the statement is false.

EPA has previously cautioned data submitters with respect to current TSCA that they may be subject to criminal penalties under 18 U.S.C. 1001 if they knowingly and willfully make a false statement in connection with the assertion of a CBI claim. 76 FR 50830 (2011). EPA believes that a requirement to affirmatively certify that the CBI claims accompanying submitted information are true and correct plays an important role in supporting the enforceability of existing criminal law respecting false claims to the United States government. This was among the reasons for establishing such a requirement for submissions under the Chemical Data Reporting rule. 40 CFR 711.15(b)(1).

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, February 24, 2016 11:28 AM
To: Kaiser, Sven-Erik
Subject: Section 8/14 - false claims on CBI

Sven

Has EPA ever enforced against a company for making a false CBI claim?

Is there sufficient authority under 697 for EPA to do so? Does requiring companies to certify their CBI claims alter existing enforcement authority?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 12:38 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA on Senate 26(m) "rule promulgated"

Michal,
This TA responds to the request on section 26(m) language on "promulgated."

Question: Look at section 26(m) in the senate offer. Does "rule promulgated" mean finalized? What if it was "rule promulgated or proposed"?

m) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Response: The term "promulgated" essentially means finalized or issued. Adding the words "or proposed" expands the scope of the provision beyond final actions, but we do not think that would be necessary and are not sure there would be any real effect to that. That is because any final action taken after the enactment of the revised Act would need to comply with the revised Act regardless of whether a proposal is "saved" and the agency may need to issue a supplemental proposal to address changed statutory requirements before taking final action. Adding the term "proposal" would also appear incongruous as everything else section 26(m) refers to is a final action of some sort (i.e., "order issued" or "exemption established"), which a proposal is not.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 25, 2016 at 5:25:37 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on partial risk evaluations

Look at section 26(m) in the senate offer. Does "rule promulgated" mean finalized? What if it was "rule promulgated or proposed"?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 2:18 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on Senate Discussion Draft
Attachments: Markey.TSCA TA on Discussion Draft.docx

Michal, This responds to your request for TA on the Discussion Draft document. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]

Sent: Friday, March 04, 2016 10:57 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: FW: discussion draft and and outline of some changes toward House

Nichole

First of all, I wanted to extend my thanks to your team for all of the TA they provided over the past weeks (well, ok, months). It was all much appreciated, considered and hopefully well -integrated into this document.

Second of all, I'd like to request that EPA take a look at the Discussion Draft document and provide any feedback or suggestions for clarifying changes that are appropriate. I'd be particularly interested to learn whether EPA believes that the changes made to Senate sections 3A and 4A (both have been deleted, but elements of 3A have been shifted to section 26 and a more streamlined prioritization section has been shifted into section 6(b)) address some or all of the issues with those sections that EPA raised in its 1/20/16 letter to Congress.

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

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March 4 Request for TA:

Second of all, I'd like to request that EPA take a look at the Discussion Draft document and provide any feedback or suggestions for clarifying changes that are appropriate. I'd be particularly interested to learn whether EPA believes that the changes made to Senate sections 3A and 4A (both have been deleted, but elements of 3A have been shifted to section 26 and a more streamlined prioritization section has been shifted into section 6(b)) address some or all of the issues with those sections that EPA raised in its 1/20/16 letter to Congress.

Response:
EPA flags the following as particularly significant issues that have arisen as a result of the latest revisions to sections 6 and 26 (primarily relating to the removal of sections 3A and 4A). Throughout, "Senate Bill" refers to TSCA as it would be amended by the bill that passed in December 2016, and "Senate Offer" refers to TSCA as amended in the recently circulated offer text.

1. Clear duty to initiate risk management proceedings without regard to cost or other non-risk factors

The prior Senate bill was very clear that a negative safety determination necessarily triggered a duty to promulgate a risk management rule. Senate Bill § 6(d)(1). There is no decision-making step between the decision that a chemical substance does not meet the safety standard and the initiation of rulemaking to ensure that the chemical substance does meet the safety standard. But the Senate offer could be construed to introduce such a decision-making step, unconstrained by the key proviso to evaluate unreasonable risk "without consideration of costs or other non-risk factors."
See Senate Offer § 6(c)(1), which indicates that the deciding factor in whether rulemaking proceeds is whether EPA determines that that the chemical substance presents an unreasonable risk, "based on" a risk evaluation conducted in accordance with subsection (b)(4)(A). But that risk evaluation presumably already contains the unreasonable risk decision, since the purpose of the risk evaluation was to make such a decision, "without consideration of costs or other non-risk factors." Some might read 6(c)(1) as directing EPA to do a second unreasonable risk determination (i.e., building on the first but this time introducing cost and other non-risk factors) to decide whether risk management rulemaking is warranted.

There is a simple fix: § 6(c)(1): "If, ~~based on~~ in a risk evaluation conducted in accordance with subsection (b)(4)(A), the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment. . ."

2. Non-comprehensive menu of regulatory options.

EPA identified some possible limitations created by TSCA section 6(a) menu of requirements that EPA can impose in section 6 rulemaking. Although the Senate bill as passed expanded this menu to make it more comprehensive, those improvements have been eliminated in the draft. For example, under the

draft, EPA would lack express authority to regulate manufacture, processing or distribution in a way that does not involve a complete or partial prohibition or volume or concentration limitation.
Some might argue that "catch-all" regulatory authority over existing chemical substances was thereby withheld, especially since it was elsewhere supplied with respect to new chemical substances. Senate Offer § 5(d)(3)(C)(v). Beyond this specific issue, we do not see an obvious logic for having different menus of options under sections 5 and 6, and some might try to use the differences to argue for differing authorities or approaches under these two sections.

In operation, the lack of comprehensive menu of requirements could drive EPA to impose regulation that is more burdensome than necessary.

3. Clear and Enforceable Deadlines

Senate Offer § 6(b)(4)(G) provides that EPA "shall conduct and publish a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the dae on which the Administrator initiates a risk evaluation." We imagine the intent, consistent with Senate Bill § 6(a)(4), was to specify that EPA "shall ~~conduct~~ **complete** and publish a risk evaluation . . ." This is correction is important to ensure that the deadlines for completing risk evaluations are enforceable.

4. Impact of Developing Policies and Procedures on Other Aspects of Program Implementation

Senate Bill § 6(b) ensures risk evaluations and risk management actions can proceed even in the absence of completed policies and procedures, and thereby prevents general disputes about methodological issues from impeding the actual implementation of TSCA Reform during the early years after enactment. In the Senate Bill, the point of reference was to policies and procedures under §§ 3A and 4A. These included the prioritization procedures (Senate Bill § 4A(a)(1)) and the risk evaluation procedures (Senate Bill §3A(h)(2)). Senate Bill § 6(b) has since been relocated to Senate Offer § 26(j)(4), and instead of referring to policies and procedures under §§ 3A and 4A, it refers to policies and procedures that are established § 26. Some may therefore argue that it is therefore inoperative with respect to the key policies and procedures established under § 6 (for conducting prioritization and risk evaluations). These were clearly encompassed by Senate Bill § 6(b), but they are no longer clearly encompassed by Senate Offer § 26(j)(4). A simple drafting fix would be to revise §26(j)(4) as follows:

(4) Prior Actions and Notice of Existing Information.—

(A) PRIOR-INITIATED EVALUATIONS.—

(i) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under this ~~section~~ **Act**.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(ii) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As **relevant** policies and procedures under this ~~**section**~~ **Act** are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing risk evaluations.

(B) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination or rule solely because the action was completed prior to the completion of a policy or procedure established under this ~~**section**~~ **Act**.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Tuesday, March 15, 2016 4:35 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA Request - CBI - 14(c)(4) and 14(d)(1)(D)

Michal – this TA responds to your request on CBI – sections 14(c)(4) and 14(d)(1)(D). Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Are senate 14(c)(B)(4)
Or 14(d)(1)(D)
Needed? Redundant? In conflict with other parts of the section?

Response:
14(c)(4): EPA does not believe this provision is redundant. It is a provision of current TSCA section 14(b)(2)) that we think helps bolster the argument that health and safety information (and a broader class of information under S 697) that is releasable under TSCA also cannot be protected under other authority in the event of a FOIA request.

14(d)(1)(D):The requirement in 14(a) (also referenced in 14(b)) that the information be exempt under FOIA Exemption 4, already includes an implied requirement that the information not already be publicly available.

However, the way 14(d)(1)(D) is worded, that "no person may assert a claim", suggests that EPA could treat such information as not subject to a confidentiality claim at all. It would make it easier to deny a claim, but EPA would need to have procedures in place to ensure that the information is not simply disclosed without at the very least an internal verification that it is subject to 14(d)(1)(D).

> **From:** Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
> **Sent:** Tuesday, March 15, 2016 11:28 AM
> **To:** Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
> **Cc:** Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
> **Subject:** More senate 14 qs
>
> Are senate 14(c)(B)(4)
> Or 14(d)(1)(D)
> Needed? Redundant? In conflict with other parts of the section?
> Thx

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, January 04, 2016 5:42 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request - 8 questions
Attachments: Markey.TSCA TA.8 questions.docx

Michal – in response to your request, see attached EPA's technical assistance. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 17, 2015 12:31 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: TA request

Hi Nichole

I was hoping to get responses to the following questions:

1) The safety standard approach in this bill uses underlying TSCA's "unreasonable risk" lexicon. In the changes to TSCA section 6, EPA is told not to include costs or other non-risk factors, which presumably allows EPA to make chemical safety decisions exclusively using scientific risk assessments. Do you agree with my assessment of this as far as Section 6 goes? Does EPA also believe that this bill ensures that EPA cannot consider costs or other non-risk factors in other sections of TSCA, and if not, why not? Does this bill address in totality throughout TSCA the "unreasonable risk" argument that was used to overturn the asbestos ban?
2) Does EPA have the authority it needs under this bill to require testing of chemicals? Is the current TSCA catch-22 test finding which requires EPA to find that there may be an unreasonable risk BEFORE requiring such testing removed in this language?
3) Does EPA have sufficient flexibility in this bill to appropriately consider costs of rulemaking, while also ensuring that it will not have undue litigation risk or incur analytic burden if it does not find that a cost-effective regulatory option that will address the risk the chemical poses exists?
4) Is EPA required to assess the safety of a new chemical on vulnerable subpopulations under this bill?
5) Does this text give EPA the clear authority to set priorities for conducting risk evaluations that allows EPA to study chemicals that are ubiquitous OR known/suspected hazards? Are there deadlines that are enforceable for EPA to conduct its chemical safety responsibilities in this bill?
6) Does this bill require manufacturers to substantiate new and old CBI claims? Can data relevant to health and safety be treated as CBI under this bill? Does EPA have authority under this bill to provide CBI to state and local governments when necessary?

7) Does this bill ensure that EPA will get sufficient industry and other resources to fund its TSCA activities? How does this bill's funding for EPA intersect with the ability for industry to request that EPA perform risk evaluations under the bill?
8) Does the bill give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, March 14, 2016 3:39 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - CBI

Michal,
This responds to your inquiry on House and Senate CBI language. The four factors below

(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—
(i) taken reasonable measures to protect the confidentiality of the information;
(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering

are essentially the type of analysis EPA typically uses when determining whether information is entitled to confidential treatment. Cf. 40 CFR 2.208. EPA would expect to continue applying the same types of analyses under the House and Senate bills, since EPA's analysis is based on relevant case law under APA section 552(b)(4) -- the confidentiality standard under TSCA, which is retained in both bills. The fourth factor, whether the information is discoverable through other means, is not normally separated out, but is part of the analysis.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 14, 2016 12:57 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall) ; Deveny, Adrian (Merkley)
Subject: TA request - CBI

Sven

Just quickly trying to compare a couple elements of House v Senate section 14. See below. Recognizing that EPA had a question about House (iii) below and electronic reporting, do you think that an assertion of CBI would require an applicant for protection to demonstrate what is in Senate (i), (iii) and (iv) even if it was not specified that they had to do so in statute, ie is that sort of analysis is embedded in what a justification of a CBI designation means?

Thanks
Michal

House

''(i) justification for each designation of confidentiality;

''(ii) a certification that the information is not otherwise publicly available; and

''(iii) separate copies of all submitted information, with one copy containing and one copy excluding the information to which the request applies.

Senate

(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, December 16, 2015 10:34 AM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on RE: TA request
Attachments: Markey.TSCA TA.Pace of Risk Evaluations.docx

Michal,
This responds to your technical assistance request related to ensuring the pace of risk evaluations. Please see the attached redline version and let me know if any additional questions.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, December 15, 2015 11:01 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: TA request

Hi Nichole

Can you possibly suggest some ways, drafted to House text, that would ensure that the House pace of 10 risk evaluations/year would be assured?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
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Washington, DC 20510
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Connect with Senator Markey

(b) Risk Evaluations.--Section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)) is amended to read as follows:

``(b) Risk Evaluations.--

``(1) In general.--The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.

``(2) Applying requirements.--The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection, without consideration of costs or other non-risk factors, that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.

``(3) Conducting risk evaluation.--

``(A) Required risk evaluations.--The Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance if--

``(i) the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use; or

``(ii) a manufacturer of the chemical substance requests such a risk evaluation in a form and manner prescribed by the Administrator.

``(B) TSCA work plan chemicals.--The Administrator may, without making a determination under subparagraph (A)(i), conduct and publish the results of a risk evaluation under this subsection for a chemical substance that, on the date of enactment of the TSCA Modernization Act of 2015, is listed in the TSCA Work Plan for Chemical Assessments published by the Administrator.

``(4) Requirements.--In conducting a risk evaluation under this subsection, the Administrator shall--

``(A) integrate and assess information on hazards and exposures for all of the intended conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations;

``(B) not consider information on cost and other factors not directly related to health or the environment;

``(C) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance;

``(D) describe the weight of the scientific evidence for identified hazard and exposure;

``(E) consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur; and

``(F) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency,

including contractor costs, of conducting the risk evaluation are paid for by the manufacturer.

``(5) Deadlines.--

``(A) Risk evaluations.--The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later than--

``(i) 3 years after the date on which the Administrator--

``(I) makes a determination under paragraph (3)(A)(i); or

``(II) begins the risk evaluation under paragraph (3)(B); or

``(ii) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), 2 years after the later of the date on which--

``(I) the manufacturer requests the risk evaluation; or

``(II) if applicable, the risk evaluation is initiated pursuant to subparagraph (B).

``(B) Deadline adjustment.--If the Administrator receives ~~more requests for risk evaluations under paragraph (3)(A)(ii) than the Administrator has resources to conduct by the deadline under subparagraph (A)(ii)(I) (taking into account the requirement in paragraph (4)(F))~~ requests for risk evaluations under paragraph (3)(A)(ii) that would, if granted, cause the number of ongoing risk evaluations under paragraph (3)(A)(ii) to exceed [X] percent of the total number of ongoing risk evaluations, then the Administrator shall--

Commented [A1]: This protection doesn't clearly kick in until the demands of completing industry-initiated risk evaluations have matched EPA's total processing capacity. If the objective is to ensure a certain proportionality between the chemicals being reviewed on EPA's initiative and those being reviewed on industry initiative, that should be addressed more directly.

``(i) shall not accept any such requests for risk evaluations under paragraph (3)(A)(ii) until a sufficient number of risk evaluations under (3)(A)(i) or (3)(B) have been initiated to ensure that the specified percentage of risk evaluations under (3)(A)(ii) is not exceeded ~~that exceed the Administrator's allotted resources as soon as resources for such risk evaluations are available~~; and

``(ii) shall not collect a fee under section 26 from the manufacturer for a risk evaluation under (3)(A)(ii) until the Administrator initiates the risk evaluation.

``(C) Subsection (a) rules.--If, based on a risk evaluation conducted under this subsection, the Administrator determines, without consideration of costs or other non-risk factors, that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall--

``(i) propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and

``(ii) publish in the Federal Register a final rule not later than 2 years after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A).

``(D) Extension.--If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the

Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than--

``(i) 90 days after receipt of such additional information; or

``(ii) 2 years after the deadline being extended under this subparagraph.

``(6) Determinations of no unreasonable risk.--

``(A) Notice and comment.--Not later than 30 days before publishing a final determination under this subsection that a chemical substance does not and will not present an unreasonable risk of injury to health or the environment, the Administrator shall make a preliminary determination to such effect and provide public notice of, and an opportunity for comment regarding, such preliminary determination.

``(B) Potentially exposed subpopulations.--The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator determines that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to one or more potentially exposed subpopulations.

``(C) Final action.--A final determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment shall be considered a final agency action.

``(7) Minimum number.--~~Subject to the availability of appropriations,~~ Tthe Administrator shall initiate 10 or more risk evaluations under paragraphs (3)(A)(i) or (3)(B) in each

fiscal year beginning in the fiscal year of the date of enactment of the TSCA Modernization Act of 2015.''.

*****

SEC. 8. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended--

(1) in subsection (b)(1)--

(A) by striking ``of a reasonable fee'';

(B) by inserting ``of a fee that is sufficient and not more than reasonably necessary'' after ``section 4 or 5'';

(C) by inserting ``, or who requests a risk evaluation under section 6(b)(3)(A)(ii),'' before ``to defray the cost'';

(D) by striking ``this Act'' and inserting ``the provision of this title for which such fee is collected'';~~ and~~

E) by inserting after the text added by (D) "In the case of a fee collected from a person who requests a risk evaluation under section 6(b)(3)(A)(ii), in addition to defraying the cost of administering that provision, the fee shall also be sufficient and not more than necessary to carry out obligations under 6(b)(5)(C) resulting from the Administrator's completion of the risk evaluation."; and

Commented [A2]: To ensure that industry funds risk management arising from industry requests, in addition to the evaluations, to avoid swallowing Agency resources for other priorities

(FE) by striking ``Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100.'' and inserting ``Such rules shall provide for lower fees for small business concerns.'';

(2) by adding at the end of subsection (b) the following:

``(3) Fund.--

``(A) Establishment.--There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the `Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

``(B) Collection and deposit of fees.--The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.

``(C) Crediting and availability of fees.--On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1), and in carrying out obligations under 6(b)(5)(C) resulting from the Administrator's completion of a risk evaluation that was requested under section 6(b)(3)(A)(ii).

``(D) Use of funds by administrator.--Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use only in administering the provisions of this title for which the fees are collected.

``(E) Accounting and auditing.--

``(i) Accounting.--The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period

covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

``(ii) Auditing.--

``(I) In general.--For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

``(II) Components of audit.--The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of--

``(aa) the fees collected and amounts disbursed under this subsection;

``(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

``(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

``(III) Federal responsibility.--The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Monday, February 08, 2016 5:07 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on replacement parts
Attachments: Markey. TSCA TA.replacement parts.docx

Michal,
Attached please find technical assistance that responds to your request on replacement parts. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 02, 2016 10:29 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Hi Sven

Your past TA provided an option to allow EPA to exempt replacement parts designed prior to the effective date of a TSCA regulation from that regulation if EPA found that the replacement parts would not be impracticable to replace/redesign. After receiving feedback from colleagues, I have re-drafted it to make the presumption be exemption, rather than the presumption being non-exemption. Can you take a look, suggest any changes and describe any concerns you might have with implementation?

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments.

(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations;

(iv) shall exempt replacement parts designed prior to the effective date of the rule, unless the Administrator finds

(1) that the replacement parts are not impracticable to redesign or replace without redesigning the articles of which they are components, or
(2) such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations;

Commented [A1]: This is the Senate replacement part language, with additional text added re potentially exposed subpopulations, but your text below appears to be a revision to the House replacement parts language. Not sure what we are comparing the new suggested language to. And is there a reason the new suggested language is numbered (iv)? Which bill would it go into?

Commented [A2]: It would likely be difficult for EPA to determine when a replacement part was designed, and the design could pre-date the rule by years, making it challenging for EPA to implement the exemption.

Commented [A3]: For readability, it might be better if this said "can practicably be redesigned or replaced".

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, March 03, 2016 6:08 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on Risk Evaluation Process
Attachments: Markey,TSCA TA.Risk Evaluation Process.docx

Michal - the attached document responds to your TA request on risk evaluation process. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 02, 2016 6:18 PM
To: Kaiser, Sven-Erik
Subject: quick turnaround pls

Does this work

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine, without consideration of costs or other non-risk factors whether a chemical substance presents, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.

(B) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (B), for a chemical substance–
  (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
  (ii) subject to subparagraph (F), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (C), be subjected to a risk evaluation.

(D) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.

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255 Dirksen Senate Office Building
Washington, DC 20510

202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 12:09 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,
This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,
Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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TA Request:

Does this work

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine, without consideration of costs or other non-risk factors, whether a chemical substance presents, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.

(B) Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) The Administrator shall conduct and publish a risk evaluation, in accordance with the process established in the rule promulgated under subparagraph (B), for a chemical substance–

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (F), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (C), be subjected to a risk evaluation.

(D) The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.

TA Response:

We have interpreted your question broadly, as asking whether this new paragraph would suffice to ensure that unreasonable risk is applied without consideration of cost and non-risk factors, throughout all the stages of risk evaluation and risk management contemplated under the bill.

This new language (subparagraph 4(A), in particular) makes clear that when EPA conducts a risk evaluation it must determine whether or not unreasonable risk exists without consideration of

costs or other non-risk factors. We have suggested two minor edits to help drive this point home.

However, there are three particularly critical issues with respect to the stages of risk evaluation and risk management contemplated under the bill that are not resolved in this paragraph. While it is possible to draft language in other provisions of the bill that address these issues, EPA flags them here for your reference:

- Whether EPA is authorized to conduct and publish a risk evaluation prior to finalizing the rule under (4)(B).
    - We understand your intent would be: Yes, EPA can proceed under 4(C) even if the rule under 4(B) does not yet exist.

- Whether EPA may decline to proceed to risk management rulemaking, based on a subsequent and broader unreasonable risk analysis that includes cost considerations or other non-risk factors, and on that broader basis take no further action on a determination under (4)(A) that a chemical substance presents an unreasonable risk.
    - We understand your intent would be: No, EPA cannot use cost or non-risk factors to decide that proceeding to risk management is unwarranted, after already deciding that a chemical substance presents an unreasonable risk under paragraph (4)(A).

- Whether, in the course of rulemaking, EPA may adopt a broader view of what constitutes an unreasonable risk than would be allowed under (4)(A) (i.e., to incorporate cost or other non-risk factors) and design the rule to ensure that the chemical substance does not pose an unreasonable risk, where unreasonable risk is understood under that broader view.
    - We understand your intent would be: No, EPA cannot use cost or non-risk factors to readjust what unreasonable risk means in the context of a risk management rule. EPA must design the rule to eliminate the unreasonable risk, determined without regard to costs or other non-risk factors, except to the extent that exemption authority (e.g., to establish exemptions for critical uses) is used. EPA's use of the exemption authority results in certain unreasonable risks persisting, not in a re-definition of what unreasonable risk means. Moreover, EPA would be able to consider costs and other non-risk factors in selecting among the regulatory options that would address the risk identified in (4)(A).

If your intention was to create a definition of "unreasonable risk" that can simply be referenced in other provisions, we do not believe your draft (4)(A) does that in a reliable way, because it literally specifies only the manner in which EPA must determine unreasonable risk for purposes of a risk evaluation rather than clearly defining the term.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Here is a revision of subparagraph (A) that we believe would better accomplish that objective:

> *(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine~~, without consideration of costs or other non-risk factors,~~ whether a chemical substance presents, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator. Under this paragraph and under any other provision in the Act in which sub-paragraph (4)(A) is referenced, "unreasonable risk of injury to health or the environment" means a risk of injury to health or the environment that is unreasonable without regard to costs or other non-risk factors.-*

To adequately follow through on this approach, it would still be necessary to include references (4)(A) in appropriate locations, and to furthermore clarify that 4(C) does not bar proceeding with a risk evaluation in the event that the risk evaluation process rule has not yet been completed.

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Friday, March 25, 2016 12:04 PM
To: 'Freedhoff, Michal (Markey)'; Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA Request on Section 4(a)(1)

Michal – please see TA below responding to the request on section 4(a)(1). Please let me know if any questions. Thanks,
Sven

Question

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.
(a) TESTING REQUIREMENTS

(1) IN GENERAL. – The Administrator may, by rule, order, or consent agreement, require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary –
(A) to review a notice under section 5(d) or to perform a risk evaluation under section 6;
(B) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);
(C) pursuant to section 12(a)(4); or
(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

EPA Response:

We have a number of concerns with the suggested removal of order authority from all or part of the Senate's Section 4(a)(1).

EPA's difficulty in requiring development of information on chemicals is a major problem under current law. There are two main issues. First, existing law requires EPA to make a risk or exposure finding in order to require testing under Section 4. When data on a chemical is lacking, it is very challenging for EPA to exercise its Section 4 authorities. Second, even if EPA is able to clear the initial Section 4 hurdle, it must then go through a lengthy rulemaking to require the testing and get the data - potentially a 3-5 year process. Continuation of the rulemaking requirement unnecessarily delays EPA from getting the information it needs to assess a chemical's safety, and would almost certainly prevent EPA from meeting statutory deadlines under the House and Senate bills for completing risk evaluations

With respect to the argument you described, it is hypothetically possible that EPA might promulgate a testing requirement concurrently with a section 6(a) or 5(d) rule. But it is also possible that the testing need will not become apparent until the restriction under 5 or 6 is already in place. If successful implementation of a protective requirement is dependent on information to be developed under Section 4, it is imperative that EPA have order authority to require that information in an expeditious manner.

The Administration's Principles very clearly call for EPA to be given "the necessary authority and tools…to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals." The recent Administration's views letter echos that sentiment, commending both the House and Senate for providing EPA with new order authority in Section 4. We'd underscore the importance of order authority again here.

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 23, 2016 3:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 4

Sven

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Thursday, February 11, 2016 6:01 PM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA Request on section 5 'unreasonable risk' and may/likely

Michal,
This responds to your TA request on the unreasonable risk finding.

Respecting an affirmative negative finding (i.e., one that would be used to justify restricting a new chemical substance), it would be easier for EPA to justify a determination that a chemical substance "may present" an unreasonable risk than to justify a determination a chemical substance is "likely to present" an unreasonable risk. "Likely" implies a greater degree of certainty about the effects of a chemical than "may present."

Respecting an affirmative positive finding (i.e., that a new chemical is OK to proceed to manufacture) note that there is no opposite-of-"may present" standard to be found under current TSCA. "Unlikely to present" an unreasonable risk is not the opposite finding, because a chemical substance could potentially meet both the "unlikely to present" an unreasonable risk standard and the "may present" an unreasonable risk standard. The opposite of the "may present" finding could perhaps be framed as: "There is not a reasonable basis to conclude that the chemical substance may present an unreasonable risk."

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 11, 2016 at 10:12:10 AM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: section 5 TA request - 'unreasonable risk' and may/likely

Sven

Existing TSCA section 5 refers to determinations that a chemical substance 'presents or will present' an unreasonable risk, and 'presents or may present' an unreasonable risk, depending on which part of Section 5 we are talking about.

S 697 alters this construct by including a safety standard definition, and switches the finding to "likely" or "not likely" to meet the safety standard.

If one were switching back to the 'unreasonable risk' lexicon and away from a 'safety standard' lexicon, but retaining the Senate requirement that EPA make affirmative determinations about new chemicals, does EPA see a difference between "presents or may present" and "is likely to present" an unreasonable risk? I do, in that I see "may present" as a lower bar that is consistent with current TSCA. I am interested in your team's views.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

Tillery, Loreto

From: Kaiser, Sven-Erik
Sent: Wednesday, March 02, 2016 10:24 AM
To: 'Freedhoff, Michal (Markey)'
Subject: Sen. Markey TSCA TA request on section 5 PBTs
Attachments: Markey.TSCA TA.section 5 PBTs.docx

Michal – please see the attached document in response to your TA request on PBTs. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 29, 2016 1:59 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Markey TSCA TA PBTs on New Chemicals

Sven:

Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

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Washington, DC 20510

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 7:20 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA PBTs on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions
Thanks,
Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and
b) The time to do so would not extend the PMN process beyond allotted 90-day deadline.

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:22 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

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Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the

proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.

Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

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Question: Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Answer:

We do not think a general direction to take action "consistent with" the referenced policy document would reliably lead to a more stringent outcome than current S. 697, which clearly directs EPA to achieve the more stringent of: (1) What is necessary to meet the safety standard and (2) Exposure reduction to the maximum extent practicable. First, the PBT policy statement at 64 FR 60202 (1999) describes actions that EPA will generally take under section 5 as to PBTs, but it also clearly states that the document provides "general guidance" that is not binding on EPA or outside parties, so EPA could take actions other than the generally recommended control actions that would be consistent with the policy. Second, your draft language references successor policy statements, without circumscribing the content of such statements, so the language ultimately provides little bounding for EPA decisions with respect to new PBT chemicals. Third, since legislative history would reflect that the new language was a change from a strict prior directive to achieve more than the Section 6 safety standard, there would likely be an implication from this revision that Congress intended to allow EPA more flexibility.

You also ask for suggested tweaks, but we would need to better understand your policy objectives, and the perceived deficiencies of the current bill text, to provide language.

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You also ask for suggested tweaks, but we would need to better understand your policy objectives, and the perceived deficiencies of the current bill text, to provide language.